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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,186	02/08/2002	Joel Richard	03715.0109	8142

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EXAMINER	
KISHORE, GOLLAMUDI S	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,186	RICHARD ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,11-34,37,40 and 41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 11-34, 37 and 40-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 8-8-05 is acknowledged.

Claims included in the prosecution are 1-8, 11-34, 37 and 40-41.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-8, 11-34, 37 and 40-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amended claim 1 is confusing. The original claims were drawn to a method of administering a composition having microparticles having specific characteristics. The added limitations now are confusing. Is it a product prepared by a specific process? If so, the steps should have been recited. Lines 6-7 recite amounts of the organic solvent (3.5 % to 25 %). The last two lines of the claim recite the amount of the organic solvent as less than 500 ppm. When is this organic solvent removed?

In view of applicant's amendments, the 102 rejection has been withdrawn.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-8, 11-34, 37 and 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over either EP 0706821 or FR 2753639 by themselves or in combination with either WO 98/31346 or WO 96/29998.

EP discloses polymeric micro particles coated with a surfactant (lecithin) prepared by the same method. The particles contain an active principle such as calcitonin. The mean diameter of the particles 20 nm to 100 microns with an apparent density between 0.02 g/cm3 and 0.8 g/cm3 (columns, 2, 3, 5, 6, 7, 11, Examples and claims 1, 5,6, 11, 17 and 20).

FR discloses polymeric coated micro particles prepared by the same method using a super critical fluid and an organic solvent. The particles have a diameter of 20 nm to 500 microns with an apparent density between 0.02 g/cm3 to 0.8 g/cm3. The active agents include peptides (note pages 2, 3, 4, 8, Examples and claims 1, 2, 5, 9-14 and 16). US 6,183,783 (of record) appears to be an English equivalent for FR (abstract, col. 3, line 13 through col. 5, line 8; col. 5, line 35 through col. 6, line 53; Examples and claims of US patent).

What is lacking in EP and FR is the mode of administration of the microspheres.

WO discloses polymeric micro particles for inhalation. The particles are coated with surfactant such as a phospholipid, DPPC, DPPG for example. The particles contain a variety of active principles such as hormones, both protein and non-protein type (insulin, estrogens), antiasthmotics (albuterol). The particles have density of less than 0.4 g/cm3 and a mean diameter of 5-30 microns (note pages 8, 9, 10, 20 and 21,

Examples 1, 5-11). While WO discloses generic 'phosphoglycerides' and phospholipids, it does not teach claimed individual phosphatidylethanolamine and phosphatidylserine. However, in view of WO's exemplification using phosphatidylcholines and its generic teachings, it is deemed obvious to use any phospholipid with the reasonable expectation of success. WO also does not teach the claimed anti-asthmatic agent, beclametasone. However, in view of WO's teachings of other anti-asthmatic agents such as cromolyn, salmetrol, formeterol and albuterol, it is deemed obvious to one of ordinary skill in the art to use any known anti-asthmatic agent with a reasonable expectation of success.

WO 96 discloses polymeric coated micro particles prepared by the similar method using a super critical fluid and an organic solvent for the pulmonary administration of active agents such as calcitonin (abstract, page 5, lines 4-12, Examples and claims).

The administration of the microparticles of EP or FR via pulmonary route would have been obvious to one of ordinary skill in the art since the mode of administration is the choice of the practitioner of the art to obtain the best possible results. One of ordinary skill in the art would be motivated to administer these microparticles with a reasonable expectation of success since the references of WO 98 and 96 both teach microparticles prepared by similar methods can be administered by pulmonary route.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that EP does not specify a mean diameter of 1-15 microns. This argument is not persuasive since EP teaches a range of the particles

which includes claimed range and it is within the skill of the art to prepare particles of desired sizes depending upon the mode of administration and to obtain the best possible results. Applicant argues that EP does not disclose microparticles with an active principle/coating agent mass ratio between 95/5 and 80/20 or an external layer comprising a residual quantity of organic solvent of less than 500 ppm. These arguments are not persuasive. The calculated value of the active agent to the coating agent from the examples in EP is 70 % (1.3 g coating agent and 3 g of active agent in Example 1). This value is closer to the 80/20 claimed by applicant and it is within the skill of the art to manipulate the amounts of the active agents based on the teachings of EP. With regard to less than 500 ppm argued by applicant, the examiner points out that as recited in the claims, the organic solvent is optional and this amount of the organic solvent is only when it is used in the method; the method in EP does not require organic solvent.

Applicant's arguments with regard to FR are not persuasive. Applicant once again argues that FR does not teach the mean diameter of between 1 and 15 microns. This argument is not persuasive since the claimed range falls within the range taught by the reference and it is within the skill of the art to prepare particles of desired sizes depending upon the mode of administration and to obtain the best possible results. Applicant's argument that FR does not disclose microparticles with an active principle/coating agent mass ratio between 95/5 and 80/20 are not persuasive since the reference teaches 25 to 95 percent active agent (page 9, lines 16-17 of FR and col. 6, lines 51-53 of the English equivalent, 6,183,783).

Applicant argues that WO 98 and WO 96 do not cure the deficiencies of EP or FR since they do not teach particle sizes between 1 and micrometers are not persuasive. WO 98 teaches particles ranges, which encompass instant ranges, and the reference teaches the inhalation method. Instant lower size of 1 micrometer is close to the upper limit in WO 96 and the particles are for pulmonary delivery of the active agents.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK